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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,097	09/19/2006	Ana Isabel Sanz Molinero	4559-053854	1132

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EXAMINER	
KUMAR, VINOD	

ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
10/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,097	SANZ MOLINERO ET AL.	
	Examiner	Art Unit	
	VINOD KUMAR	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,25,28,32 and 52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,25,28,32 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/1/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/1/2010 has been entered.

Status of objections and rejections

2. Applicant's response filed in the papers of 2/1/2010 and 2/16/2010 is entered.

3. Claims 22, 25, 28, 32 and 52 are pending. Claims 1-21, 23-24, 26-27, 29-31, 33-51 and 53 are cancelled. Claims 22, 25, 28, 32 and 52 are examined on merits in the present Office action.

4. Objection to claims 29-31 and 53 is withdrawn in light of cancellations of these claims filed in the paper of 2/1/2010.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Rejections of claim 32 under 35 U.S.C. 112, 2nd paragraph is withdrawn in light of claim amendments filed in the paper of 2/1/2010.

7. Rejections of claim 32 under 35 U.S.C. 112, 1st paragraph are withdrawn in light of claim amendments filed in the paper of 2/1/2010.

8. Rejection of claim 29 under 35 U.S.C. 103(a) as being unpatentable over Fukuda et al. (European Patent Publication No. EP 1143002, A1, Published October 10, 2001, Applicant's

IDS), and in view of Chan et al. (Plant Molecular Biology, 22: 491-506, 1993) is withdrawn in light of cancellation of the claim filed in the paper of 2/1/2010.

9. Rejection of claim 53 under 35 U.S.C. 103(a) as being unpatentable over Fukuda et al. (European Patent Publication No. EP 1143002, A1, Published October 10, 2001, Applicant's IDS), and in view of Christensen et al. (Transgenic Research 5, 213-218, 1996) is withdrawn in light of cancellation of the claim filed in the paper of 2/1/2010.

Election/Restriction

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

11. Claim 32 remains objected to because of the following informalities:

Claim 32 remains objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Parent claim 22 is directed to SEQ ID NO: 1 encoding SEQ ID NO: 2. Dependent claim 32 fails to limit the parent claim because it encompasses a nucleotide sequence that may not comprise the nucleotide sequence of SEQ ID NO: 1 but is capable of hybridizing to SEQ ID NO: 1 under stringent conditions recited in the amended claim 32. The stringent conditions of hybridization would also encompass hybridization of nucleotide sequences other than SEQ ID NO: 1. Furthermore, claim 32 fails the infringement test because

claim 32 would conceivably be infringed by a nucleotide sequence which does not comprise the nucleotide sequence of SEQ ID NO: 1 but is capable of hybridizing under "stringent conditions" to SEQ ID NO: 1, whereas, the nucleotide sequence (other than SEQ ID NO: 1) that hybridizes under stringent conditions to SEQ ID NO: 1 would not infringe claim 22. See MPEP § 608.01(n).

It is noted that Applicant's response filed in the paper of 2/1/2010 does not address the objection as outlined above. It is important to note that claim 32 is broader in scope than the parent claim 22 as discussed above.

In Claim 32, it is suggested to change "60 degree C." to --60° C--

Claim Rejections - 35 USC § 103

12. Claims 22, 25, 28, 32 and 52 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fukuda et al. (European Patent Publication No. EP 1143002, A1, Published October 10, 2001, Applicant's IDS), and further in view of Wu et al. (Plant cell Physiol. 39:885-889, 1998) for the reasons of record stated in the Office action mailed 9/28/2009.

Applicant traverses the rejection in the paper filed 2/1/2010.

Applicant primarily argues that Fukuda et al. do not teach expressing SEQ ID NO: 1 encoding SEQ ID NO: 2 from a seed-specific promoter. Applicant also argues that Wu et al. do not teach NHX protein of SEQ ID NO: 2. Applicant further argues that expression of NHX protein of SEQ ID NO: 2 from a seed-specific promoter produces unexpected results as instantly claimed. Applicant cites Valerie Frankard's declaration (filed 2/1/2010) to argue that expressing NHX (SEQ ID NO: 2) from a shoot or root-specific promoter failed to increase plant yield. Applicant further argues that Wu et al. do not discuss using seed-specific promoters for any

purpose other than to improve seeds and thus one skilled in the art together with teachings of Wu et al. would not be led to try to improve any plant part other than seeds (response, pages 5-7).

Applicant's arguments are carefully considered but are deemed to be unpersuasive.

Applicant's arguments are not persuasive to suggest that expressing NHX (SEQ ID NO: 2) from a seed-specific promoter produced unexpected results of increased yield. Applicant's attention is specifically drawn to page 17 (lines 1-10 and 20-24) of the specification, wherein Applicant clearly states that the instantly claimed invention can be practiced by using constitutive promoter. It is also noted that Applicant had previously claimed expressing NHX (SEQ ID NO: 2) from a constitutive promoter, such as ubiquitin promoter (see claims 29 and 53, now cancelled; filed 1/27/2009). Furthermore data presented in Applicant's declaration is directed to leaf or root specific promoters. Thus Applicant's arguments are contradicting the statements made in the specification.

It is maintained that Fukuda et al. teach a method of making a transgenic rice (monocotyledonous) plant comprising transforming a rice plant with a nucleic acid sequence encoding the OsNHX1 protein of SEQ ID NO: 2, which has 100% sequence identity to instant SEQ ID NO: 2. The nucleic acid sequence (SEQ ID NO: 1) taught in the reference has also 100% sequence identity to instant SEQ ID NO: 1. The reference also teaches that the nucleic sequence used in making said transgenic plant is from rice, which is a monocotyledonous plant belonging to family Poaceae. The reference also teaches that the transformation comprises introducing and over-expressing the nucleic acid sequence encoding the OsNHX1 protein. The reference also teaches that the overexpression of the nucleic acid sequence resulted in the increased expression of OsNHX1 protein in said rice plant. See in particular, pages 7-8, example

1, paragraphs 0042-0044; pages 8-9, example 2-3, paragraphs 0046-0049; pages 21-22, claims 1-14, and 16; figures 1-3; SEQ ID NOs: 1 and 2. Fukuda et al. also teach that the nucleic acid sequence encoding the NHX (OsNHX1) protein was in sense orientation and operably linked to a CaMV 35S promoter. See page 9, paragraph 0049, line 4. Fukuda et al. also teach that rice is a monocotyledonous crop that has very low tolerance to salt, and is considered a salt sensitive plant species. See page 3, line 34.

It is further maintained that Wu et al. teach rice seed-specific promoter(s) that are active in transgenic seed-tissues. Wu et al. also teach an endosperm-specific prolamin promoter. See in particular, page 885, abstract; page 886, figure 1, table 1; page 887, figure 2.

It is maintained that it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of making a transgenic monocotyledonous plant (rice) as taught by Fukuda et al., to substitute the CaMV 35S promoter with a seed-specific or endosperm specific promoter of Wu et al., to obtain a transgenic rice plant and transgenic rice seeds derived thereof, expressing Fukuda et al. OsNHX1 protein from Wu et al. promoter.

It is further maintained that it would have been obvious and within the scope of an ordinary skill in the art to use any seed-specific promoter including the prolamin seed-specific promoter of Wu et al. in over-expressing Fukuda et al. OsNHX1 protein specifically in seed tissues with a reasonable expectation of success.

It is further maintained that given Fukuda et al. teach that rice is a naturally occurring salt-sensitive plant species, one of ordinary skill in the art would have been motivated to

specifically overexpress Fukuda et al. OsNHX1 protein in the seeds so that the transgenic rice seeds thrive during seed maturation and germination when grown under naturally occurring salt concentrations with a reasonable expectation of success. It may be emphasized that a naturally occurring soil in which most of the plant species grow normally would be considered a non-salt stress condition.

Thus, while one of ordinary skill in the art would have expressed Fukuda et al. OsNHX1 protein in a plant for the purpose of obtaining an abiotic (salt) stress tolerant transgenic plant (e.g. rice in the instant case) and/or seeds derived therefrom as discussed above, it would have been obvious that said transgenic plant would have also exhibited any other characteristics including increased seed yield (e.g. increased seed number and seed weight) with a reasonable expectation of success because said increased yield would have been due to Fukuda et al. OsNHX1 protein (100% identity to instant SEQ ID NO: 2) over-expression in the transgenic plant seed.

It is important to note that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art would have arrived at the claimed invention with a reasonable expectation of success by combining the teachings of Fukuda et al. and Wu et al. as discussed above.

It is important to note that obviousness does not require an absolute certainty of success

but merely a reasonable expectation thereof, so long as the motivation or suggestion to combine the teaching of the cited references is known or disclosed in the prior art and is obvious to one skilled in the art and this is sufficient to establish a *prima facie* case of obviousness. In the instant case, one of ordinary skill in the art would have used teachings of the prior art as discussed above to arrive at the claimed invention with a reasonable expectation of success.

It is therefore, maintained that the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art.

Conclusions

13. Claims 22, 25, 28, 32 and 52 remain rejected.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Vinod Kumar/

Primary Examiner, Art Unit 1638